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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,909	09/18/2001	Marc Pelletier	40853-01-5028-01	8433

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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,909	PELLETIER ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed April 15, 2003 (certificate of mailing April 10, 2003), has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The terminal disclaimer filed on April 15, 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,323,008, has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1-36 are pending and are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-10, 19-26 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandekerckhove et al (Glycobiology 2(6):541-548 (1992)).

Vandekerckhove discloses the preparation of α-2,3-sialyllactose by contacting lactose with α-2,3-trans-sialidase from *Trypanosoma cruzi* in the presence of various sialyloligosaccharides. See, e.g., abstract, page 542 (Table 1). See also page 547, left column, paragraph entitled "Enzyme activity measurements", disclosing two procedures for the transfer of sialic acid to lactose, as well as the purification of the resulting product.

Note that this rejection has been extended to cover claims 1, 2, 4-10, 19-26 and 36. Claims 1, 2, 4-10 and 36 require the enzyme to be contacted with "a dairy source." Applicant's specification, at page 11, lines 1-3, defines a "dairy source" as "a product of lactation in a mammal, a substance made by the product, or a byproduct thereof." Lactose is a product of lactation in a mammal. Thus, the lactose used in Vandekerckhove as a sialic acid acceptor for the trans-sialidase is encompassed by the term "dairy source," as that term is defined in applicant's specification.

Claims 19-26 require the enzyme to be contacted with "a cheese processing waste stream." Applicant's specification, at page 11, lines 18-23, states that a cheese processing waste stream "refers to a byproduct of cheese manufacture and includes . . . lactose." Thus, the lactose used in Vandekerckhove as a

sialic acid acceptor for the trans-sialidase is encompassed by the term "cheese processing waste stream," as that term is defined in applicant's specification.

Note still further that the non-recombinantly produced enzyme of Vandekerckhove would be identical to a recombinantly produced enzyme, and therefore anticipatory of those claims reciting recombinant trans-sialidase. A holding of anticipation is clearly proper.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant has indeed amended claim 36 to recite the production of oligosaccharides from a dairy source. However, as discussed above, applicant's specification, at page 11, lines 1-3, defines a "dairy source" as "a product of lactation in a mammal, a substance made by the product, or a byproduct thereof." Lactose is a product of lactation in a mammal. As further discussed above, the specification, at page 11, lines 18-23, states that a cheese processing waste stream "refers to a byproduct of cheese manufacture and includes . . . lactose." Thus, the lactose used in Vandekerckhove as a sialic acid acceptor for the trans-sialidase is encompassed by the terms "dairy source" and "cheese processing waste stream," using the

definitions supplied in applicant's specification. A holding of anticipation over the cited claims is therefore required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandekerckhove et al (Glycobiology 2(6):541-548 (1992)) in view of Brian et al (U.S. Pat. 5,575,916) and Ito et al (U.S. Pat. 5,409,817).

As discussed above with respect to § 102(b), Vandekerckhove discloses the preparation of α-2,3-sialyllactose by contacting

lactose with α-2,3-trans-sialidase in the presence of various sialyloligosaccharides. Vandekerckhove differs from the cited claims in that Vandekerckhove does not use the dairy products recited in claims 7, 11 and 27 as substrate for the enzyme, nor does Vandekerckhove disclose the additional cheese processing steps recited in the claims. However, Brian et al disclose that dairy products, including cheese processing waste, contain sialyloligosaccharides which are substrates for the α-2,3-trans-sialidase. Thus, the artisan of ordinary skill at the time of applicant's invention would have deemed obvious that one could have prepared sialyloligosaccharides by the claimed method of contacting a cheese processing waste stream with an α-2,3-trans-sialidase. Motivation for such a process clearly would have been derived from the known utility of the resulting product, such as the presence of the α-2,3-sialyllactose produced by the enzyme's action in sialyl Lewis x, disclosed for example in the Ito patent. Motivation for using the claimed recovery steps would have been obvious in view of the fact that Brian discloses that the claimed recovery steps were suitable for the recovery of sialyloligosaccharides from products such as cheese waste streams. Motivation for using a recombinantly produced enzyme would have been derived from the fact that the artisan of ordinary would have expected a recombinantly produced enzyme to

have functioned at least equivalently to the enzyme produced from the natural source. A holding of obviousness over the cited claims is therefore proper.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant urges that Ito teaches away from the claimed invention because Ito teaches that the *T. cruzi* trans-sialidase is not useful in synthesis reactions due to the reversible nature of the catalyzed reaction. Applicant urges that Ito couples the trans-sialidase reaction to a sialyltransferase, so as to shift the equilibrium to favor the trans-sialidase reaction, therefore teaching away from the claimed invention.

However, while Ito uses the sialyltransferase to drive the trans-sialidase reaction, Ito does not teach that the trans-sialidase cannot function without the sialyltransferase. Rather, Ito teaches that it is "difficult to drive the equilibrium in favor of the desired sialoside." Ito, column 3, lines 63-64. Moreover, one of ordinary skill would know that the trans-sialidase is in fact active in the absence of sialyltransferase, as evidenced by Vandekerckhove's successful preparation of a large variety of sialyloligosaccharides in the absence of sialyltransferase. Thus, while Ito may teach that the use of sialyltransferase would be a preferred method of

driving the trans-sialidase reaction, the prior art taken as a whole demonstrates that the sialyltransferase is not necessary for the trans-sialidase reaction.

Moreover, even if it were conceded that Ito "teaches away" from using a trans-sialidase by itself, it is respectfully pointed out that applicant's claims recite the claimed process in open "comprising" language, which does not exclude the use of additional enzymes. That is, Ito does not teach away from the invention ***as claimed***, because the invention ***as claimed***, due to the "open" language present in the claims, encompasses the use of the additional enzymes used in Ito. The obviousness rejection is therefore properly maintained.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
June 9, 2003